

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Hannon et al. Confirmation No.: 4804
Application No: 09/866,557 Art Unit: 1635
Filed: May 24, 2001 Examiner: S. McGarry
Title: METHODS AND COMPOSITIONS FOR RNA INTERFERENCE

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

In accordance with Applicants' duty of candor and good faith in dealing with the Office, as set forth in 37 CFR §1.56(a), and in accordance with 37 CFR §1.97 and §1.98, this Information Disclosure Statement, and the accompanying form PTO/SB/08, is being filed to bring to the attention of the Office certain facts pertaining to the prosecution of U.S. patent application 09/866,557 (hereinafter the "present application"), and also pertaining to U.S. patent applications 60/243,097, 09/858,862, 10/055,797, 10/350,798, 10/997,086, 11/330,043, 11/791,554, 11/894,676, 12/152,655, and 12/152,837 and to international patent applications PCT/US01/08345, PCT/US03/01963, and PCT/US05/42488.

This Information Disclosure statement is being filed concurrently with a Request for Continued Examination (RCE). The Director is hereby authorized to charge the fee for the filing of an RCE, as required by 37 CFR 1.17(e), or any other fees associated with the filing of this paper, to Deposit Account No. 08-0219.

Applicants request that the Examiner initial and return a copy of the enclosed form PTO-SB-08 with the next communication.

The **Facts** disclosed are listed beginning on page 2 of this paper.

The **Exhibits** to this Information Disclosure Statement are listed on page 6 of this paper and on the accompanying form PTO/SB/08.

Additional **Remarks** are provided on page 7 of this paper.

FACTS

The following facts are brought to the attention of the Office:

1. International Patent Application PCT/US98/27233, which was published on July 1, 1999 with International Publication Number WO/99/32619, and which lists Andrew Fire as the first named inventor/applicant, was cited to the Office during the prosecution of the present application in the Supplemental Information Disclosure Statement of November 26, 2004. International Patent Application PCT/US98/27233 is referred to hereinafter as the "Fire PCT."

2. U.S. Patent No. 6,506,559, which issued on January 14, 2003, and which lists Andrew Fire as the first named inventor, was cited to the Office during the prosecution of the present application in the Supplemental Information Disclosure Statement of January 7, 2005. U.S. Patent No. 6,506,559 is referred to hereinafter as the "Fire patent."

3. The Fire PCT and the Fire patent are referred to collectively hereinafter as the "Fire specifications."

4. The specification of the present application contains numerous sections of text that are the same as, or very similar to, text in the Fire specifications. A "marked-up" version of the present application is attached hereto as Exhibit A. In this marked-up version of the present application, text that is the same as text in the Fire specifications is highlighted.

5. U.S. patent application numbers 60/189,739, 60/243,097, 09/858,862, 10/055,797, 10/350,798, 10/997,086, 11/330,043, 11/791,554, 11/894,676, 12/152,655, and 12/152,837

(hereinafter the “related U.S. patent applications”), and international patent applications PCT/US01/08345, PCT/US03/01963, and PCT/US05/42488, are related to the present application. These related patent applications, together with the present application, are referred to herein as “the Hannon RNAi applications.” With the exception of U.S. patent application number 60/189,739, all of the Hannon RNAi applications contain sections of text that are the same as, or very similar to, text in the specification the Fire specifications. Information Disclosure Statements disclosing this fact are being filed for each of the affected Hannon RNAi applications that are currently pending. The first filed of the Hannon RNAi applications to contain sections of text that are the same as, or very similar to, text in the specification the Fire specifications, was U.S. provisional patent application 60/243,097 (“the ‘097 application”), to which the present application claims priority. A “marked-up” version of the ‘097 application is attached hereto as Exhibit B. In this marked-up version of the ‘097 application, text that is the same as text in the Fire specifications is highlighted.

6. Cold Spring Harbor Laboratory (hereinafter the “CSHL”) is the assignee of the entire right, title, and interest in the present application.

7. Dr. Vladimir Drozdoff, J.D. (hereinafter Dr. Drozdoff) is a Senior Licensing Associate and Patent Attorney for CSHL’s Office of Technology Transfer. Dr. Drozdoff first began working at CSHL on February 11, 2008. As indicated in the Declaration of Dr. Drozdoff, attached hereto as Exhibit C, Dr. Drozdoff first became aware of the apparent “copying” of text from the Fire specifications into the Hannon RNAi applications upon reviewing the Office Action of 9/4/2007 in the file of the present application (hereinafter the “Office Action”) during the week of February 25, 2008. The Office Action states, on both page 8 and page 10, that “*the disclosure of cell[s]/organisms of the instant specification at pages 21-22 is essentially verbatim of the disclosure of Fire et al. at column 8.*” As indicated in the attached Declaration of Dr. Drozdoff, after reviewing the Office Action, Dr. Drozdoff compared the text of the Fire specifications with the text of the present application and with the text of the ‘097 provisional application and thereby discovered the full extent of the apparent “copying” of text from the Fire specifications. The textual similarities between the Fire specifications and the present application can be seen in the “marked-

up” version of the present application attached hereto as Exhibit A. The textual similarities between the Fire specifications and the ‘097 application can be seen in the “marked-up” version of the ‘097 application attached hereto as Exhibit B.

8. Mr. John Maroney, J.D. (hereinafter Mr. Maroney) is the Vice President, Legal Counsel, and Director of CSHL’s Office of Technology Transfer. As indicated in the Declaration of Mr. Maroney, attached hereto as Exhibit D, Mr. Maroney first became aware of the apparent “copying” of text from the Fire specifications into the Hannon RNAi applications upon being advised of the same by Dr. Drozdoff on March 3, 2008.

9. Professor Gregory Hannon (hereinafter “Professor Hannon”) is a named inventor of the currently pending claims and is a Professor and Howard Hughes Medical Institute (HHMI) Investigator at CSHL. As indicated in the Declaration of Professor Hannon, attached hereto as Exhibit E, Professor Hannon first became aware of the apparent “copying” of text from the Fire specifications into the Hannon RNAi applications upon being advised of the same by Dr. Drozdoff and Mr. Maroney on March 18, 2008.

10. As indicated in the Declarations of Dr. Drozdoff, Mr. Maroney, and Professor Hannon, attached hereto as Exhibits C, D, and E, respectively, to the extent that any papers were filed with the Office, or any statements were made to the Office, during the prosecution of the present application, including any statements made to the Office about the Fire patent or the Fire PCT or any statements made about the present application that involved sections that are the same as sections of the Fire specifications, all such statements were made without any knowledge on the part of Dr. Drozdoff, Mr. Maroney, or Professor Hannon, or, to the best of their knowledge, on the part of CSHL, that the specification of the present application contains text that is the same as, or very similar to, text from the Fire specifications.

11. As indicated in the Declarations of Dr. Drozdoff and Mr. Maroney, attached hereto as Exhibits C and D respectively, after learning of the of the apparent “copying” of text from the Fire

specifications into the Hannon RNAi applications, Dr. Drozdoff and Mr. Maroney, acting on behalf of CSHL, diligently sought new counsel to advise CSHL in connection with the present application.

12. On May 8, 2008, CSHL engaged the undersigned as new counsel to advise CSHL in connection with the present application.

13. Between May 8, 2008 and June 13, 2008, Dr. Drozdoff and Mr. Maroney, acting on behalf of CSHL, had numerous meetings and teleconferences with Dr. Jane M. Love (the undersigned) and others of Wilmer Cutler Pickering Hale and Dorr, LLP (hereinafter WCPHD).

14. On June 13, 2008 CSHL revoked all previous powers of attorney given in the present application, and appointed the undersigned and those practitioners associated with Customer number 28089 as Attorneys of record for the present application, by executing a Revocation of Power of Attorney with New Power of Attorney and Change of Correspondence Address form (form PTO/SB/82).

15. On June 13, 2008, Dr. Love filed the above mentioned executed form PTO/SB/82 with the Office.

16. On June 13, 2008. Dr. Love telephoned Examiners McGarry, Vivlmore, and Chong, and SPE Schultz, to schedule an interview to discuss the facts described herein and in the attached Declarations.

17. On July 28, 2008. Dr. Love, together with Mr. Maroney, Dr. Drozdoff, and Professor Hannon, conducted an interview at the Patent Office with Examiners McGarry, Vivlmore, and Chong, and SPE Schultz, to discuss the facts described herein and in the attached Declarations.

EXHIBITS

The following Exhibits are submitted with this Information Disclosure Statement:

- Exhibit A: Marked-up copy of the present application 09/866,557 (filed 5/24/2001)
- Exhibit B: Marked-up copy of provisional patent application 60/243,097 (filed 10/24/2000)
- Exhibit C: Declaration of Dr. Vladimir Drozdoff (executed 8/5/2008)
- Exhibit D: Declaration of Mr. John Maroney (executed 8/5/2008)
- Exhibit E: Declaration of Professor Gregory Hannon (executed 8/5/2008)
- Exhibit F: Letter of April 22, 2008 (referred to in Exhibit D)
- Exhibit G: Letter of April 28, 2008 (referred to in Exhibit D)
- Exhibit H: Letter of April 29, 2008 (referred to in Exhibit D)
- Exhibit I: Letter of May 9, 2008 (referred to in Exhibit D)
- Exhibit J: Letter of June 4, 2008 (referred to in Exhibit D)
- Exhibit K: Letter of June 13, 2008 (referred to in Exhibit D)

Exhibits A and B provide marked-up copies of the present application and provisional patent application 60/243,097, respectively, in which text that is the same as text in the Fire specifications is highlighted. To the best of my knowledge, these marked-up documents are accurate.

In these marked-up applications, the numerals in the margins denote the page numbers of the corresponding sections of the Fire PCT.

In Exhibit A (the present application - 09/866,557, as published), the following paragraphs contain copied text: [0037], [0120]-[0126], [0128]-[0131], [0133]-[0139], [0141]-[0144], and [0146-0151].

In Exhibit B (provisional patent application 60/243,097), the following pages contain copied text: page 3 (final two paragraphs), pages 4-13 (all paragraphs), and page 14 (first three paragraphs).

REMARKS

This paper is being filed to advise the Office of the above facts relating to the apparent “copying” of certain sections of the Fire specifications during the drafting of the present application, and to advise the Office of Mr. Maroney’s, Dr. Drozdoff’s, Professor Hannon’s, the undersigned’s, and, to the best of Mr. Maroney’s, Dr. Drozdoff’s and Professor Hannon’s knowledge, CSHL’s, lack of knowledge of, or complicity in, the same. This paper is also being filed to advise the Office that any previous statements made during the prosecution of the present application, and any previous declarations made by the inventors or others, were made without any knowledge, on the part of Mr. Maroney, Dr. Drozdoff, Professor Hannon, the undersigned, or, to the best of Mr. Maroney’s, Dr. Drozdoff’s and Professor Hannon’s knowledge, anyone at CSHL, that the present application contains text that appears to have been copied from the Fire specifications.

If any further information is needed in relation to the above facts and remarks, the Examiner is invited to contact the undersigned at his convenience.

Dated: August 22, 2008

/Jane M. Love, Ph. D./ _____
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